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IN THE

Supreme Court of the United States

SANDOZ INC.,

Petitioner,

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Respondents.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER AND CROSS-RESPONDENT SANDOZ INC.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae America's Health Insurance Plans ("AHIP") files this brief in support of the petitioner and cross-respondent Sandoz Inc.

AHIP is the national trade association representing the health insurance community. It advocates for public policies that expand access to affordable healthcare coverage for all Americans through a competitive marketplace that fosters choice, quality and innovation. Along with its predecessors, AHIP has over 50 years of experience in the industry. AHIP's members provide health and supplemental benefits through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. As a result, AHIP's members have broad experience working with hospitals, physicians, patients, employers, state governments, the federal government, pharmaceutical, biotechnology and device companies, and other healthcare stakeholders to ensure patients have access to needed treatments and medical services – including through robust price competition in prescription drug markets.

This case raises critical issues for health insurers concerning the proper interpretation of the 2010 Biosimilars Price Competition and Innovation Act

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[1]All parties have consented to the filing of this brief, and letters reflecting such consent accompany this brief. No counsel for a party authored this brief in whole or in part; no counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief; and no one other than *amicus*, its members, or its counsel made such a contribution.

("BPCIA"),[2] through which Congress created an expedited approval pathway for "biosimilars." Biosimilars are highly similar or interchangeable versions of U.S. Food and Drug Administration ("FDA")-licensed branded biologic medicines. (A brand biologic in this context is known as a "reference product" and its license holder as a "Reference Product Sponsor" or "RPS."). Congress enacted the BPCIA to increase competition in biologic markets by allowing for the expedited introduction of lower-cost biosimilars, thereby (1) accelerating patients' access to medicines that are among the most medically necessary and expensive drugs on the market today and (2) helping control spiraling health care costs, which are increasingly due to spending on prescription drugs – especially high-priced drugs like branded biologics. Health insurance plans (and the consumers they serve) are among the principal beneficiaries of the BPCIA's biosimilars approval regime.

Both statutory interpretation issues in this case implicate the BPCIA's overarching goal of expediting patients' access to affordable, lifesaving medicines.

The *first* issue is whether the Federal Circuit was correct in holding that the BPCIA's 180-day notice of commercial marketing provision should be read to delay patients' access to biosimilars for *six additional months beyond the statute's express 12-year market exclusivity period for reference products*. AHIP agrees with Sandoz that the Federal Circuit's interpretation

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[2] Patient Protection & Affordable Care Act, Pub. L. No. 111-48, §§ 7001-03, 124 Stat. 119, 804-21 (2010).

of the notice provision was *incorrect* and if upheld would impose significant, unintended costs on the U.S. healthcare system and consumers.

The *second* issue is whether the Federal Circuit was correct in holding that a biosimilar applicant is not required to share its application with the RPS to initiate the BPCIA's patent dispute resolution process – known as the "patent dance." AHIP agrees with Sandoz that the Federal Circuit's interpretation of the application-sharing provision was *correct*, that biosimilar applicants may forgo the patent dance if doing so affords a quicker, more efficient path to market, and that this reading of the statute squares with Congress's goal of speeding access to affordable lifesaving medicines.

AHIP and its members have a strong interest in ensuring that courts interpret the BPCIA consistent with Congress's overriding policy goal of ensuring competition and patients' access to biosimilars. Drug costs are a significant driver of premiums and out-of-pocket costs for consumers, and biologic costs are in turn a significant driver of rising drug costs. A robust biosimilar system is vital to patients' ability to access these important treatments and to relief for consumers, employers, and government health insurance programs from unrelenting drug cost increases. Proper resolution of the issues in this case is critical to implementing Congress's intent in enacting the BPCIA and to health insurance plans' ability to provide consumers with quality coverage at premiums that are affordable.

STATEMENT

A. The Role of Prescription Drug Costs in the Upward Spiral of Health Care Spending.

Prescription drug costs in the United States are increasing at an unsustainable rate. U.S. spending on prescription drugs, including biologics, jumped 12.6 percent to $424 billion in 2014, and "drug spending growth is estimated to have remained elevated in 2015." Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending* 3, Table 1 (Mar. 8, 2016) ("2016 ASPE Report").[3] In 2015, Spending for drugs covered under the Medicare Part B program (which include outpatient prescription drugs, such as biologics, that are administered by physicians rather than by patients themselves) totaled $24.6 billion, a 14 percent increase from 2014. Ctrs. for Medicare and Medicaid Servs. ("CMS"), *Medicare Drug Spending Dashboard* Table 1b (Nov. 14, 2016).[4] Likewise, 2015 spending for drugs, including biologics, in the Medicare Part D prescription drug program increased by 13 percent from 2014, to $138 billion. *Id.*, Table 1a. Drug spending as part of the Medicaid program increased by 24 percent from 2013 to 2014. Medicaid and CHIP Payment and Access Commission

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[3]https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf.

[4]http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-14.html.

(MACPAC), *Report to Congress on Medicaid and CHIP* 14 (June 2016).[5]

Spending on prescription drugs, including biologics, has also increased as a share of overall health care costs. According to the Department of Health and Human Services, drug spending rose from 7 percent of total health care spending in the 1990s to 15.3 percent of spending in 2013 and is expected to further rise to 16.8 percent of total health care spending by 2018. 2016 ASPE Report 3. The drug spending growth rate has exceeded rates of spending growth in other health care sectors: For example, prescription drug spending in 2014 grew by 9 percent, compared to the 6.3 percent growth rate for physician and clinical services and the 5.6 percent growth rate for hospital expenditures for that year. Ctrs. for Medicare and Medicaid Servs., *NHE Fact Sheet* (last modified Dec. 2, 2016).[6] Moreover, the CMS data only includes retail prescription drug spending, thus excluding medicines administered in hospital settings, which are typically among the most expensive drugs.

Higher prescription drug prices have a direct impact on insurance premiums, thereby hurting consumers. One analysis modeled the impact of a hypothetical specialty drug (a category that includes most biologics) costing $100,000 per treated patient that would increase total health care costs by $250 for

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[5]https://www.macpac.gov/wp-content/uploads/2016/06/June-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

[6]https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

every 0.25 percent of the population using the drug. Because underlying health costs are the basis for setting insurance premiums, under this model, a specialty drug used by just 5 percent of the population would lead to an almost 15 percent increase in premiums. Bradford R. Hirsch, Suresh Balu & Kevin A. Schulman, *The Impact of Specialty Pharmaceuticals As Drivers Of Health Care Costs*, Health Affairs 33, No. 10, 1714-20 (2014).

In short, increased prescription drug spending has been a significant driver of rising healthcare costs overall. Prescription drug spending is also a significant driver of *consumer* healthcare costs, both through direct out-of-pocket spending and through contributions to premiums. Consumers – as well as hospitals, providers, employers, and state Medicaid directors – have expressed increasing frustration regarding drug costs that show no signs of slowing down.

Health insurance plans have used a number of solutions to help mitigate the impact of high drug costs on patients, businesses that offer their employees health care coverage, and taxpayers who fund government healthcare programs such as Medicare Parts B and D. In particular, they have encouraged the use of less expensive but equally safe and effective generic versions of brand-name small-molecule drugs – for example, through tiered formularies (*i.e.*, lists of covered drugs) in which consumers have lower cost-sharing obligations when they use generic drugs. Congress created an expedited approval pathway for small-molecule generic drugs in 1984 when it passed the Hatch-Waxman amendments

to the Food, Drug and Cosmetic Act. Thanks to the availability, prescribing, and dispensing of lower-cost generic drugs, the U.S. healthcare system saved $227 billion between 2005 and 2015. IMS Health and Generic Pharm. Ass'n, *2016 Generic Drug Savings and Access Report* 5 (8th ed. 2016).[7] Indeed, the use of generic drugs has become pervasive, to the great benefit of consumers of health insurance, making up 89 percent of prescriptions dispensed but only 27 percent of total medicine spending. *Id.*

B. The Promise of Biosimilars and the BPCIA.

Biosimilars represent the next frontier in the fight against rising drug costs. Biologics, unlike the relatively simple small-molecule drugs covered under Hatch-Waxman, are complex, large-molecule medicines derived from living organisms and are used to treat a range of conditions, including rheumatoid arthritis, plaque psoriasis, Crohn's disease, lymphoma, leukemia, breast cancer, and diabetes. Biologics are among the most expensive drug products in the United States and account for an ever increasing share of U.S. prescription drug costs. Federal Trade Comm'n, Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposal on Competition, 78 Fed. Reg. 68,840 (Nov. 15, 2013) (noting that biologics are "among the most important pharmaceutical products in the United States" and "comprise the fastest growing sector within pharmaceuticals."). In 2010, spending on biologics in the United States was $67

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[7]http://www.gphaonline.org/media/generic-drug-savings-2016/index.html

billion, or approximately 20 percent of overall drug spending. IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010* 4, 6 (Apr. 2011).[8] By 2013, spending on biologics in the United States had increased nearly 40 percent to $92 billion, or approximately 28 percent (also a 40 percent increase) of overall drug spending. Alex Brill, *The Economic Viability of a U.S. Biosimilars Industry*, Matrix Global Advisors 4 (Feb. 2015).[9] *See also* 2016 ASPE Report 6-7 (noting that spending on "specialty drugs," which include biologics, rose from $14.5 billion in 2009 to $27.1 billion in 2015 – an annual average growth rate of 11 percent); *id.* 7 (spending on specialty drugs as a percentage of spending on all retail drugs increased from 5.7 percent to 7.6 percent – a 33.3 percent increase – between 2009-2014). Nine of the 10 top selling drugs in the world are biologics. Evaluate Grp., *EP Vantage 2017 Preview* 5 (Dec. 2016) ("*Evaluate Report*").[10]

On average, biologics cost $45 per day, compared to $2 per day for small-molecule drugs. Steve Pociask, *Lifesaving Drugs at Lower Costs*, Am. Consumer Inst. Ctr. for Citizen Research ConsumerGram 2 (July 22, 2014).[11] Some biologics cost tens or even hundreds of

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[8]https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf.

[9]http://www.matrixglobaladvisors.com/storage/MGA_biosimilars_2015_web.pdf.

[10]info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[11]http://www.theamericanconsumer.org/2014/07/new-consumergram-lifesaving-drugs-at-lower-costs/.

thousands of dollars per patient per year. Humira® (adalimumab), which treats rheumatoid arthritis and other conditions and is the top selling drug in the world (approximately $17.6 billion projected sales in 2017 (*Evaluate Report* 5)), costs over $50,000/year. Judith A. Johnson, *FDA Regulation of Follow-On Biologics*, Cong. Research Serv., RL34045, 1 (Apr. 26, 2010) ("CRS Report"). The discounted price of a two-week dose of Humira® in 2009 was $630; by 2015, it had more than doubled, to $1,331. Robert Langreth, Michael Keller & Christopher Cannon, *Decoding BigPharma's Secret Drug Pricing Practices*, Bloomberg 3 (June 29, 2016).[12] Cerezyme® (imiglucerase), which treats Gaucher's Disease, costs $200,000/year. Erwin A. Blackstone & Joseph P. Fuhr, *Innovation and Competition: Will Biosimilars Succeed?*, Biotechnology Healthcare 24-27 (Spring 2012).[13] In 2014, Medicare Part B spent $1.5 billion for the non-Hodgkins lymphoma biologic Rituxan® (rituximab), an increase of nearly 25 percent since 2010. Ctrs. for Medicare and Medicaid Servs., *Medicare Drug Spending Dashboard* (Dec. 21, 2015) Chart 1b.[14] Many biologics have been on the market for a decade or more without any competition. Congress sought to address this issue through the BPCIA.

The BPCIA's expedited approval pathway allows FDA to approve a biosimilar based on the agency's previous findings of safety and efficacy for the RPS.

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[12]https://www.bloomberg.com/graphics/2016-drug-prices/.

[13]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351893/.

[14]http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-12-21.html.

This pathway, like the analogous though different Hatch-Waxman pathway for small-molecule generic drugs, serves the dual purposes of (1) reducing biosimilars' development costs; and (2) facilitating quicker FDA review, thus expediting competition and consumer access to affordable versions of life-saving medicines.

Increased competition from biosimilars holds the potential for enormous savings for the U.S. healthcare system, with one study estimating reductions in direct spending on biologics of more than $44 billion from 2014-2024. Andrew Mulcahy, Zach Pretmore & Soren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corp. (2014).[15] In Europe, where biosimilars have been marketed since 2004, projected savings from biosimilars through 2020 for three particular product classes have been estimated between €11.8 and €33.4 billion. Robert Haustein, et al., *Saving Money in the European healthcare systems with biosimilars*, 1(3-4) Generics & Biosimilars Initiative J. 120-26 (2012)[16] Other savings estimates are even more optimistic, with one large pharmacy benefit manager with extensive experience and data on biologics concluding that biosimilar versions of 11 high-priced biologics would save the U.S. healthcare system $250 billion from 2014-2024.

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[15]http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

[16]http://gabi-journal.net/saving-money-in-the-european-healthcare-systems-with-biosimilars.html.

Express Scripts, *The $250 Billion Potential of Biosimilars* (Apr. 23, 2013).[17]

Given the growing role of biologics in overall drug spending and the potential savings to the U.S. health care system and patients from biosimilars, the need for a robust biosimilar system cannot be overstated. The savings made possible by biosimilars lower premiums and out-of-pocket costs to consumers of insurance, thereby increasing access to lifesaving biologic medicines. Congress recognized all this and enacted the BPCIA to be a critical part of efforts by the health insurance industry and other stakeholders to stem the tide of spiraling health care costs that threatens to overwhelm our economy and jeopardize the public health in the 21st century.

SUMMARY OF ARGUMENT

The BPCIA's Notice of Commercial Marketing Provision.

The Federal Circuit's reading of the BPCIA's notice of commercial marketing provision (42 U.S.C. § 262(l)(8)) undermines Congress's intent and policy objectives, at enormous cost to our healthcare system. The Federal Circuit's holding that a biosimilar applicant can only give effective notice *after* FDA licenses the biosimilar effectively extends the BPCIA's express 12-year RPS exclusivity period to 12 years *and six months*. This "extra-statutory exclusivity windfall" (Pet. App. 43a-44a (Chen, J., dissenting)) rewrites the BPCIA's careful compromise between

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[17]http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars.html.

competition and innovation by delaying patients' access to more affordable, life-saving medicines for six months more than Congress expressly provided. The Federal Circuit's erroneous interpretation of the notice provisions would, if upheld, increase healthcare costs for patients, businesses providing health insurance for their employees, and insurers in a manner and to a degree that Congress did not intend. For example, one report estimates that the six-month delay in the availability of the biosimilar at issue in this case, Sandoz's Zarxio® (filgrastim), cost the U.S. healthcare system $270 million ($45 million per month).

The BPCIA's Application-Sharing Provision.

The Federal Circuit correctly held that 42 U.S.C. § 262(l)(2)(A) does not require a biosimilar applicant to share its application with the RPS (or allow an RPS to force an applicant to provide this information through an automatic private injunction). The BPCIA sets forth specific consequences if an applicant declines to provide this information – consequences which do not include allowing the RPS to obtain a court order forcing the applicant to engage in the information exchange process. This holding squares with Congress's intent in the BPCIA to give applicants the choice of triggering the patent dance or foregoing that process – whichever the applicant thinks will most efficiently serve the statute's goal of swift public access to biosimilars.

ARGUMENT

I. THE FEDERAL CIRCUIT'S READING OF THE BPCIA'S NOTICE OF COMMERCIAL MARKETING PROVISION UNDERCUTS CONGRESS'S INTENT AND IMPOSES SIGNIFICANT UNINTENDED COSTS ON THE U.S. HEALTHCARE SYSTEM AND PATIENTS.

A. The Federal Circuit's interpretation would delay access to biosimilars by six months more than Congress intended, undercutting the BPCIA's careful balance between innovation and competition.

The Federal Circuit's holding that 180-day notice of commercial marketing of a biosimilar can only be effective after FDA licensure of the biosimilar effectively grants an RPS six additional months of exclusivity, beyond the 12-year exclusivity period expressly included in the BPCIA. 42 U.S.C. § 262(k)(7)(A). Under the BPCIA's express terms and FDA's reading of the statute, FDA cannot license a biosimilar until the RPS exclusivity expires. *Id.* (providing that FDA shall not "ma[k]e effective [its licensing of a biosimilar] until the date that is 12 years after the date on which the reference product was first licensed" by FDA). *See also* FDA, Draft Guidance, *Guidance for Industry: Reference Product Exclusivity for Biologics Products Filed Under Section 351(c) of the PHS Act* 2 (Aug. 2014) (describing 12-year exclusivity as "the period of time in which . . . FDA is not permitted to license a [biosimilars

application] that references a reference product.")[18] If the applicant cannot give notice until after FDA licensure, as the Federal Circuit held, the 180-day notice period will *always* add six months to the 12-year exclusivity, even where the reference product has no patent protection at all, or where patent disputes between the applicant and RPS have been resolved.

Granting the RPS an "extra-statutory exclusivity windfall" (Pet. App. 43a-44a (Chen, J., dissenting)) not only directly conflicts with the statute's plain text (Pet. Br. 30-39); it also thwarts the carefully-calibrated structure Congress created to increase competition in biologics markets while also preserving incentives to innovate. BPCIA § 7001(b), 124 Stat. at 804. Congress sought to balance these objectives by creating the biosimilars approval pathway while also, as a *quid pro quo* for brand biologics manufacturers, expressly granting an RPS 12 years – *not 12 years and six months* – of exclusivity, before the end of which no biosimilar version of the RPS's product could be approved. *See* Thomas M. Burton, *Biosimilar Drugs Face U.S. Test: FDA Panel Will Decide Whether to Recommend Approval*, Wall St. J., Jan. 6, 2015, at 2 ("The 2010 Affordable Care Act created an abbreviated pathway for biosimilars to enter the U.S. market . . . . As a tradeoff for the industry, the law gave biologic drugs a 12-year period of exclusivity that protected them from competition from a biosimilar.")[19]

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[18]http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf.

[19]http://www.wsj.com/articles/biosimilar-drugs-face-u-s-test-1420590926.

Because every day of exclusivity gives patients one less day of access to more affordable life-saving medicines, the length of the RPS exclusivity period was a particularly hard-fought piece of the overall innovation/competition compromise struck by Congress. The Federal Trade Commission argued that no exclusivity was needed to encourage innovation given patent protections and market pricing incentives, while the Obama Administration supported an exclusivity period of only seven years. Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 787-91 (Nov. 4, 2010); CRS Report at 3. In the end, the 12-year exclusivity was "vetted exhaustively" and was the product of "a genuinely bipartisan Member-level compromise" that was "reached in the summer of 2007 [and] remained intact through three subsequent years of legislative debate" until it "found its place in the final law." 65 Food & Drug L.J. at 816-17.

In these circumstances, Congress could not possibly have intended to extend the 12-year exclusivity through the indirect means of the notice provisions. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes.") (citations omitted). Indeed, when Congress chose to extend exclusivity beyond 12 years – *e.g.*, when the RPS conducts pediatric studies on the reference product – it did so explicitly. 42 U.S.C. § 262(m)(2)(A) (where pediatric studies are conducted, the 12-year

exclusivity "[is] deemed to be 12 years and 6 months rather than 12 years.")

By its very definition and as Congress intended (subject to specific, express modifications), the 12-year exclusivity period is intended to delay access to biosimilars for *no more than* 12 years. Yet the Federal Circuit's reading of the notice provisions would frustrate this basic congressional policy choice by making the end of the exclusivity period a secondary event and the end of the notice period, 180 days later, the primary triggering event for access to biosimilars. A reading of the BPCIA that allows notice to be given pre-FDA licensure, so that the notice period and exclusivity end at the same time and patients can enjoy access to a biosimilar immediately after 12 years, is the only reading that is consistent with "the whole [BPCIA] and . . . its object and policy." *United States Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (citation omitted). See also *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme.")[20]

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[20]The Federal Circuit compounded its error by incorrectly holding that this post-licensing notice requirement and the attendant six additional months of delayed access to biosimilars could be enforced through an automatic private injunction by the RPS. AHIP agrees with Sandoz (Pet. Br. 43-56) that Congress did not intend for the notice provision to be an enforceable right unto itself and that the Federal Circuit's reading, if upheld, would reinforce the unintended delays occasioned by its extra-statutory six-month extension of the RPS exclusivity period.

B. The Federal Circuit's interpretation of the notice provision, if upheld, would impose significant costs on our healthcare system and patients.

Allowing an RPS to delay access to biosimilars for an additional six months beyond Congress's chosen 12-year exclusivity period would result in significant costs to patients, businesses that offer health care coverage to their employees, private insurers, and taxpayers who fund public programs such as Medicare and Medicaid. These costs take several forms. For those who can afford expensive branded biologics, delayed availability of less expensive biosimilar versions of these products still means more dollars spent on medicines, contributing to increased prescription drug costs. But for those who *cannot* afford expensive branded biologics, these delays may mean no access at all to needed treatments, imposing further human and systemic costs.

The history of the drug product at issue in this case – filgrastim – exemplifies the overall problem. Filgrastim is used to reduce infections in certain cancer patients during chemotherapy. FDA first approved Amgen's branded filgrastim product, Neupogen®, in 1991, and for nearly a quarter-century Neupogen® faced limited competition in the marketplace, making Amgen $1.4 billion in 2015 alone. Express Scripts Infographic, *Two Biosimilars to Save $22.7 Billion* 2 (2016) ("*Express Scripts Infographic*").[21] On March 6, 2015, long after Amgen's

[21]http://lab.express-scripts.com/lab/insights/drug-options/infographic-two-biosimilars-to-save-227-billion#sthash.MexS3dpG.dpuf.

12-year BPCIA exclusivity and any patent protection had expired, FDA approved Sandoz's filgrastim biosimilar, Zarxio®. However, because of the Federal Circuit's ruling that Amgen could obtain an injunction requiring Sandoz to give 180-day notice of commercial marketing of Zarxio® after approval, Sandoz could not market Zarxio® until September 2015,[22] depriving patients of a lower-priced filgrastim product for six months after FDA had deemed Zarxio® ready for the market. One report estimates that this delay cost the U.S. healthcare system $270 million ($45 million per month). Express Scripts, *One Giant Leap for More Affordable Specialty Drugs* (Aug. 26, 2015).[23]

Similarly, Remicade®, Janssen's branded version of infliximab, which is used to treat inflammatory conditions like Crohn's disease, was first approved by FDA in 1998 and in 2015 earned $8.4 billion. *Express Scripts Infographic* 2. Even though a biosimilar infliximab product, Pfizer's Inflectra®, was approved by FDA on April 5, 2016, the Federal Circuit's ruling meant Pfizer could not market Inflectra® until after expiration of the 180-day notice period in fall 2016. When it did launch Inflectra®, Pfizer offered its product at a 15% discount from the price for

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[22]Novartis press release, *Sandoz launches Zarxio®TM (filgrastim-sndz), the first biosimilar in the United States* (Sept. 3, 2015), http://multimediacapsule.thomsonone.com/novartis/sandoz-launches-filgrastim-sndz.

[23]http://lab.express-scripts.com/lab/insights/drug-options/one-giant-leap-for-more-affordable-specialty-drugs.

Remicade®.[24] Express Scripts estimates that the availability of Inflectra® and Zarxio® together will save the U.S. healthcare system and patients $22.7 billion over the next decade. *Express Scripts Infographic* 2.

FDA has also approved within the past six months biosimilar versions of the anti-inflammatory drugs Humira® (adalimumab), the world's biggest-selling drug, and Enbrel® (etanercept). These products have enjoyed market monopolies for 15 and 20 years, respectively. But despite FDA's approvals, competition is being delayed at least in part by the Federal Circuit's decision.

To date, FDA has only approved four biosimilars, but it currently is considering 66 biosimilars programs for 20 different reference products. John Jenkins, M.D., Director, Office of New Drugs, Center for Drug Evaluation and Research, FDA, *Biosimilars in the U.S.: Progress and Promise* 7 (Oct. 27, 2016).[25] Moreover, one study has concluded that over 70 percent of the overall costs of biologics in 2013 was represented by drugs whose 12-year exclusivities have already expired, in some cases years ago. Milliman, Inc., *Understanding Biosimilars and Projecting the*

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[24]Pfizer press release, *Pfizer Announces The U.S. Availability Of Biosimilar INFLECTRA®® (infliximab-dyyb)* (Oct. 17, 2016), http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_the_u_s_availability_of_biosimilar_Inflectra®_infliximab_dyyb.

[25]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM526935.pdf.

Cost Savings to Employers 8 (June 29, 2015).[26] Congress cannot possibly have intended that all these products could enjoy six months of additional, post-12-year-exclusivity windfall profits, at the cost of billions of dollars to the U.S. healthcare system and patients.

II. THE FEDERAL CIRCUIT'S READING OF THE BPCIA'S APPLICATION-SHARING PROVISION ADVANCES THE STATUTE'S GOAL OF EXPEDITING PATIENTS' ACCESS TO AFFORDABLE MEDICINES.

While the Federal Circuit incorrectly interpreted the BPCIA's notice provision, it correctly read the provision governing a biosimilar applicant's sharing of its application with the RPS (42 U.S.C. § 262(l)(2)(A)) to give the applicant the option of not sharing this information and forgoing the patent dance.

A. The BPCIA allows biosimilar applicants to decide whether to provide their applications under subsection (l)(2)(A) and whether thereby to initiate the patent dance.

The BPCIA provides a flexible framework with several alternative approaches by which applicants and RPS's may address patent disputes. This framework does not envision that an applicant will be forced to provide its application – which may include confidential development and manufacturing information and/or trade secrets – to the RPS. Quite the contrary. Congress expressly envisioned that an

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[26] http://us.milliman.com/insight/2015/Understanding-biosimilars-and-projecting-the-cost-savings-to-employers-Update/.

applicant might *not* share this information and clearly set forth the consequences of this choice. If the applicant does not provide its application to the RPS, the statute expressly states the RPS may immediately bring an action for a "declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(l)(9)(C). The BPCIA's amendments to the Patent Act confirm that Congress envisioned that an applicant might not share its application, providing that such a choice creates an act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii).

Because Congress specified procedural, patent-litigation based consequences in the event an applicant did not share its application with the RPS, the Federal Circuit correctly declined to infer additional remedies, such as an automatic private injunction requiring the applicant to provide the application. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001)) ("[P]rivate rights of action to enforce federal law must be created by Congress.").

B. Requiring all applicants to participate in the patent dance would frustrate the BPCIA's overall purpose and produce absurd results.

Congress included a range of patent dispute resolution options in the BPCIA for a reason – this layered framework was the approach most suited to advancing the overall objective of the BPCIA of expediting access to affordable medicines.

The goal of the patent provisions overall is to expedite disputes over patents that might be claimed to block the biosimilar. Congress enacted the patent dance process because it anticipated that *in certain cases*, adherence to that process would serve these ends. For example, where there is genuine uncertainty about the strength of patent protections asserted by the RPS, an extensive exchange of patent-related information might clarify the parties' positions and help determine the earliest possible date on which a biosimilar can become available.

But Congress clearly recognized there are other cases in which following these procedures might in fact *delay* resolution of the patent dispute, and where immediate litigation of this dispute, as provided for in 42 U.S.C. § 262(l)(9)(C), would best serve the BPCIA's overall goals. This is one such case. Here, Sandoz believed that Amgen had no valid patents that could block Sandoz's biosimilar version of Neupogen® and therefore concluded that the goal of access to Sandoz's Zarxio® biosimilar would best be served by immediate patent litigation, not by the information exchange contemplated in 42 U.S.C. § 262(l). Congress gave Sandoz in this case and biosimilar applicants generally the right to make that judgment. As the district court in this case explained:

> Sandoz's decision not to comply with subsection (l) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords [a biosimilars] applicant many benefits:

it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (l) lays out a process that could take up to 230 days – just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged in an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive

> information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Pet. App. 71a-72a.

Requiring that the applicant adhere to the information exchange procedures, even where doing so would delay resolution of patent disputes, would turn those procedures into ends unto themselves, rather than what Congress intended them to be – a means of advancing the BPCIA's overarching purposes. Moreover, this reading of the statute would produce the absurd results that an applicant would be required to share its application, containing confidential information and/or trade secrets, and engage in a time-consuming dispute resolution process *even where there are no disputes to be resolved*, for example where: (1) relevant patents are expected to expire before FDA completes its review of the application; (2) relevant patents will expire before the expiration of the 12-year statutory exclusivity period; or, most absurdly, (3) there are no relevant, unexpired patents even when the application is submitted. Congress carefully designed the BPCIA to avoid these nonsensical results, which directly undercut the statute's overarching purposes. *Griffin v. Oceanic Contractors*, 458 U.S. 564, 586 n.16 (1982) ("[T]o construe statutes so as to avoid results glaringly absurd . . . has long been a judicial function.").

CONCLUSION

For the foregoing reasons, the Federal Circuit's holding regarding the BPCIA's notice provision should be reversed, and its holding regarding the statute's information sharing provision should be affirmed.

Respectfully submitted.

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